UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH RESPECT TO GENERAL CAUSATION

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INTRODUCTION

Each of Plaintiffs' claims depends on a showing that the Bair Hugger patient warming system causes surgical infections.[1] Because their claims are derived from issues of medical complexity, Plaintiffs are further required to make that showing through medical expert testimony. To that end, Plaintiffs have designated three medical doctors (Drs. Samet, Jarvis, and Stonnington) as expert witnesses in these proceedings, each of whom purports to testify – to a degree of medical certainty – that the Bair Hugger system can be "ruled in" as the likely cause of Plaintiffs' alleged injuries. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) (explaining "rule in," "rule out" framework for medical causation and affirming summary judgment for defendant where plaintiff failed to come forward with admissible "rule in" expert testimony).

The problem for Plaintiffs, however, is that the opinions of their medical experts depend upon a single, weak observational study – the McGovern study – that claims to find an *association* between use of the Bair Hugger system and increased infection risk (compared to Augustine's competitor system, the HotDog) but, on its face, acknowledges that it does not show *causation*. At the outset, therefore, the *ipse dixit* opinions of Plaintiffs' medical experts should be excluded because they reach conclusions that the

[1] The term surgical site infection (SSI) encompasses periprosthetic joint infection (PJI). *See generally* ECF No. 910-19, Hickson et al., "Prophylactic Antibiotics in Elective Hip and Knee Arthroplasty," 4(11) *Bone & Joint Res.* 181 (2013) (observing that surgical site infection (SSI) includes prosthetic joint infection (PJI)); *see also* ECF No. 810-2 at 38-39, Mangram A., et al., "Guideline for prevention of surgical site infection, 1999," 27 *Am. J. of Infection* Control 97 (1999) (SSIs include "superficial incisional SSI" and "deep incisional SSI," in addition to organ/space SSI). For purposes of this brief, Defendants use the term "surgical infection" to refer to both SSI and PJI.

study authors themselves would not endorse. The McGovern study also suffers from a number of additional flaws, as explained in Defendants' briefing in support of their motion to exclude Plaintiffs' medical experts. Each of these flaws, on its own, vitiates the study's reliability. Taken together, the shortcomings leave no room for doubt that the McGovern study is fundamentally unreliable and, thus, provides no foundation for Plaintiffs' experts' opinions. For example, Professor Holford's biostatistical analysis of the underlying data – which is not rebutted by any of Plaintiffs' experts – demonstrates that one HotDog infection was mysteriously re-coded by the study authors (most likely Augustine employee, Mark Albrecht, based on when it occurred) as a Bair Hugger infection. If this re-coding of a single infection had not occurred, the study ***would not have found a statistically significant association***. Likewise, over the course of revising their drafts of the study, the study authors altered the start date of the period they chose to analyze; if they had left it as is, or chosen nearly any other month as a start date, they would have failed to find a statistically significant association. And that is even before one considers the impact of the confounders, such as a change in the antibiotics and antithrombosis drugs in the midst of the study period. As study co-author Mark Albrecht admitted (and Prof. Holford also demonstrated), factoring in these changes in drug regimen eliminates any difference between Bair Hugger and HotDog infection rates. If any one of these errors had been corrected (or avoided in the first place), the McGovern study would simply be another in a long line of studies confirming that *the Bair Hugger system does not increase the risk of surgical infections*. Instead, on the basis of flawed data and methodologies, the McGovern study has become the cornerstone of Plaintiffs' case.

The McGovern study is the *only* evidence Plaintiffs or their experts can cite – epidemiological or otherwise – that purports to demonstrate that patients whose surgeries occurred with the Bair Hugger system actually suffer a higher rate of infection than patients whose surgeries did not involve the Bair Hugger system (albeit, surgeries that used a different patient warming product). Without the McGovern study, Plaintiffs' medical experts have no basis to quantify the alleged risk on their own, no basis to claim that the Bair Hugger system actually increases surgical infections above background rates in the real world, and therefore no basis on which to offer a medical opinion that the Bair Hugger can be "ruled in" as a cause of Plaintiffs' alleged injuries. Simply put, Plaintiffs have no evidence to show there is any real-world connection (much less a causal nexus) between the Bair Hugger system and an increased risk of surgical infections.

And these proceedings are about real world medical care. Augustine's false claims, Plaintiffs' television and internet advertising, and negative publicity surrounding these proceedings are deterring doctors and hospitals from using the Bair Hugger system and other forced air warming devices. Concerned about adverse health consequences to patients, the FDA recently took the unusual step of "remind[ing] health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients." Hulse Decl. (ECF No. 751), DX1, FDA Safety Alert. Based only on their own *ipse dixit*, Plaintiffs would have this Court believe that the FDA has simply failed to consider the issue carefully enough, but Plaintiffs and their experts know perfectly well that the FDA is considering exactly the same scientific

literature that Plaintiffs' experts rely upon. There is no scientific study finding that the Bair Hugger system causes surgical infections, and when one takes into account *any* of the flaws and weaknesses of the McGovern study, there is not even one reliable study finding an *association* between Bair Hugger use and surgical infections.[2]

In sum, Plaintiffs lack reliable expert evidence of general causation, and reliable expert evidence is necessary to all of their claims, no matter which state's law applies. Their claims therefore fail as a matter of law, and this Court should grant summary judgment in favor of Defendants.

ARGUMENT

I. THE COURTS SHOULD GRANT SUMMARY JUDGMENT FOR DEFENDANTS BECAUSE PLAINTIFFS LACK ADMISSIBLE MEDICAL EXPERT OPINIONS TO DEMONSTRATE GENERAL CAUSATION

A. All of Plaintiffs' Claims Require Proof of Causation.

Defendants established in their opening brief, and Plaintiffs do not seriously dispute, that their claims require them to prove that the Bair Hugger system caused their alleged injuries. *See* ECF No. 762, Mem. in Supp. of Defs.' Mot. for S.J. With Respect to General Causation ("Def. Mem.") at 6-7 (citing *Willert v. Ortho Pharm. Corp.*, 995 F. Supp. 979, 983 (D. Minn. 1998) ("An essential element to all of plaintiffs' theories is admissible proof

[2] In addition to McGovern, Plaintiffs' medical experts also relied in their depositions on a recent publication by Augustine that purports to find an association between the Bair Hugger system and surgical site infections. As it became increasingly obvious that Augustine's publication was based upon flagrant misrepresentations of hospital data (see Defendants' reply in support of their motion to exclude Plaintiffs' medical experts, and the accompanying Declaration of Dr. Singer of South Nassau Communities Hospital), Plaintiffs told Judge Noel that they would not rely on it or seek to have it admitted at trial. Their experts have never repudiated the Augustine publication, however.

that [the product] caused [plaintiffs' illnesses]."); *Rients v. Int'l Harvester Co.*, 346 N.W.2d 359, 362 (Minn. Ct. App. 1984) ("In any theory of products liability, the plaintiff must show a causal link between the alleged defect and the injury.")).

Plaintiffs point to their unjust enrichment claim as a supposed exception to this rule, claiming that "3M blithely ignores that dispositive distinction." ECF No. 935, Pls.' Resp. in Opp'n to Defs.' Mot. for S.J. ("Pl. Mem. Opp.") at 32-33. But Plaintiffs are wrong on both counts. *See* Def. Mem. at 7-8, n.3 (noting that causation is an implicit element of an unjust enrichment claim because Plaintiffs must prove that Defendants received a benefit under circumstances that would make retention of the benefit unjust) (citing *Cromeans v. Morgan Keegan & Co., Inc.*, 303 F.R.D. 543, 558 (W.D. Mo. 2014) ("While each state in the United States describes unjust enrichment differently, the essence of such claims is that the defendant obtained a benefit, the plaintiff suffered an economic detriment as a result, and it would be inequitable for the defendant to keep the benefit under the circumstances.")); *see also In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 957 (D. Minn. 2009) ("*Viagra II*") (granting summary judgment in defendant's favor for the same reasons).

Plaintiffs go on to make the similarly unavailing argument that causation is not required to prove their consumer protection claims. *See* Pl. Mem. Opp. at 33. Plaintiffs appear to be confusing the element of causation with the element of reliance, however, as the support for their proposition amounts to a single Minnesota case that addresses whether plaintiffs are required to prove *reliance* under Minnesota consumer protection statues. *See id.* Indeed, the very case upon which Plaintiffs rely expressly confirms that a showing of

causation is indeed required for consumer protection claims – a fact which Plaintiffs "blithely ignore."[3] *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2, 13 (Minn. 2001) ("Causation is, therefore, a necessary element of an action to recover damages under [the Minnesota consumer protection statutes].") Moreover, it is well settled that Plaintiffs would not have standing to pursue their claims, unless there is a "causal connection between the injury and the conduct complained of." *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (observing that "over the years, our cases have established that the irreducible constitutional minimum of standing contains three elements," including a "causal connection between the injury and the conduct complained of").

B. In This Litigation, Medical Expert Testimony Is Required to Establish General Causation.

As discussed in Defendants' opening brief, Plaintiffs' claims arise from alleged medical injuries "requiring surgical intervention or other highly scientific technique for diagnosis," the cause of which "is not within the realm of lay understanding and must be established through expert testimony." *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000). Where such injuries are not "visible," as in this case, the requisite showing of causation requires testimony from medical experts. *See id.*; *see also Willert*, 995 F. Supp. at 983 ("Without credible expert testimony to prove *medical* causation, Plaintiffs cannot meet their burden and summary judgment is warranted.") (emphasis added). This is hardly the radical proposition that Plaintiffs suggest. *See In re Lipitor*

[3] Plaintiffs have also failed to articulate any basis on which Minnesota consumer protection statutes should – or could – be applied in the MDL, which involves only plaintiffs who residence and claim to have suffered injuries in states other than Minnesota.

(Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig., 227 F. Supp. 3d 452, 469-77 (D.S.C. 2017) ("While the specific language used by courts vary to some degree, all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience.").

Plaintiffs misconstrue the argument, claiming that Defendants are wrong to assert that no other type of expert testimony could ever support general causation. *See* Pl. Mem. Opp. at 19. But that is not Defendants' position. The point is, ***in this litigation***, Plaintiffs' remaining (engineering) experts are simply not qualified to offer an opinion about the cause of surgical infections. Even assuming the opinions of these experts were otherwise admissible (and they are not), Plaintiffs' engineering experts do not and cannot answer the threshold "rule in" question of *whether the Bair Hugger system actually causes surgical infections*, and they concede as much.[4] General causation requires a showing of both cause and effect, albeit not in any specific case. Plaintiffs' engineering experts may propose a hypothetical cause, but without the ability to connect that hypothetical cause to an actual effect (*i.e.*, that the purported dispersal of particles in the operating system results in more

[4] David, a biomedical engineer, and Koenigshofer, an HVAC engineer, both admitted their lack of medical expertise, and recognized that their expertise did not involve clinical outcomes. *See* ECF No. 932-30, David Dep. at 247:13-16, 278:18-19; 279:2-5; ECF No. 932-36, Koenigshofer Dep. at 270:8, 336:15-16. Koenigshofer admitted that he needed microbiological expertise to answer whether there is a difference between infections transmitted by direct contact and infections from endogenous sources. *See* ECF No. 932-36, Koenigshofer Dep. at 55:10-21.

surgical site infections in the real world than would otherwise have occurred if the Bair Hugger were not used), their theory is meaningless.[5]

Even where an expert articulates a theory of causation that "appears sound," expert testimony is not admissible where the "major premise" underlying the expert's theory "remains unproven." *Glastetter*, 252 F.3d at 989-92 (reviewing the experts' evidence (including animal studies, internal corporate documents, the FDA's rescission of its approval of the drug, and rechallenge/dechallenge events) and holding that it did not provide sufficient support for the experts' causation opinions, whether viewed in isolation or in the aggregate); *see also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 498–99 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) ("Causation must be based upon more than a possibility."). Against this backdrop, the deficiencies in Plaintiffs' medical experts' testimony are that much more glaring. They cannot be overcome.

C. The General Causation Opinions of Plaintiffs' Medical Experts Are Inadmissible.

Although there are a number of reasons why the testimony of Plaintiffs' medical experts fails to satisfy the requirements of Fed. R. Evid. 702 and *Daubert*, the most significant is the fact that each of Plaintiffs' medical experts relies – almost exclusively – on the McGovern study.

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[5] *See* ECF No. 751-1, Samet Dep. at 282:16-23 ("The McGovern paper supplies *only the estimate* of the risk associated for deep joint infection associated with use of the forced-air warming Bair Hugger device. So *absent the quantitative estimate* from that paper, it would be – while there would be a quite plausible mechanistic basis for increased risk, *there would not been asked [sic] an association in – in the real world*.") (emphasis added).

As the Court is aware, the McGovern study is an observational study that purports to demonstrate an association between use of the Bair Hugger system and increased risk of surgical infections. Based on the McGovern study and their review of other literature – but without performing any independent analysis of the underlying data or limitations of the study – Plaintiffs' medical experts conclude that the increased infection rate *associated* with the Bair Hugger system (as opposed to Augustine's HotDog product) is evidence that the Bair Hugger is a likely *cause* of surgical infections. Association is not equivalent to causation, however, which is why the McGovern study expressly disclaims any finding of causation. *See Reference Manual on Sci. Evid.* 336 (2d ed.) ("[I]t should be emphasized that *an association is not equivalent to causation*.") (emphasis in original); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG, 2016 WL 8739552, at *10 (D.S.C. Dec. 29, 2016) (collecting cases and confirming that "association, alone, is not sufficient to establish causation"); *see also* McGovern P.D. et al., "Forced-air warming and ultra-clean ventilation do not mix." 93-B(11) *J. Bone & Joint Surg.-Br.* 1537, 1543 (2011)[6] ("This study does not establish a causal basis for this association."). "[I]t is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proved." *Huss*, 571 F.3d at 442; *see also Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010) (excluding expert's causation testimony where, at best, it amounted to an "inspired hunch" and "the articles to

[6] DX11, Declaration of Benjamin W. Hulse in Support of Defendants' Motion to Exclude Plaintiffs' General Causation Medical Experts, ECF No. 751.

which he cites stop short of reaching the same conclusion.") (internal citations omitted); *Newkirk v. ConAgra Foods, Inc.* 727 F. Supp. 2d 1006 (E.D. Wash. 2010) (excluding plaintiff's expert who drew conclusion that the authors of the study on which he relied "explicitly stated was premature without additional data"), *aff'd*, 438 F. App'x 607 (9th Cir. 2011).

Moreover, there are a number of additional problems with the McGovern study – from the underlying data, to its methodologies and findings – that significantly undermine the study's credibility and render it fundamentally unreliable for purposes of establishing any link between the Bair Hugger system and increased surgical infection. These issues are discussed at length in various submissions before the Court.[7] The study is incredibly fragile, and factoring in any of these flaws vitiates its purported finding of an "association":

- As its co-authors admit, the study does not control for confounding factors, including changes to antibiotic and other drug regimens, that, when properly accounted for, explain the alleged association between surgical infections and the Bair Hugger system;
- There are significant, undisclosed confounders – including drastic changes to infection control policies and procedures that were not in place during the time

[7] *See* Memorandum in Support of Defendants' Motion for Summary Judgment With Respect to General Causation (ECF No. 762); Memorandum in Support of Defendants' Motion to Exclude Plaintiffs' General Causation Medical Experts (ECF No. 750); Memorandum in Support of Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Engineering Experts Daniel Koenigshofer, Michael Buck, Said Elghobashi, and Yadin David (ECF No. 805); Defendants' Opposition to Plaintiffs' Motions to Exclude Testimony of Theodore Holford and Jonathan Borak (ECF No. 913).

period in which the Bair Hugger system was studied – which (as Defendants' expert Dr. Borak explains) are highly likely to have affected infection rates;

- The study includes tabulation errors that improperly attribute at least one infection to the Bair Hugger system when it should be attributed to the HotDog (as noted above, the mysterious recoding of a single HotDog infection as a Bair Hugger infection, apparently by Augustine employee Mark Albrecht, made the difference between lack of statistical significance and statistical significance);
- As demonstrated by the drafts of the study, later in the revisions the authors changed the starting date of the period analyzed; if they had selected any earlier start date and nearly any later date, they would not have achieved statistical significance;
- The study did not even answer the question presented here, which is whether the Bair Hugger system increases surgical site infections compared to surgeries where it is not used – that is, compared to background risk. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005) (general causation opinion must demonstrate that the defendant's product increases risk above "the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical [or here, medical device] in question").

Thus, although the McGovern study purports to quantify the alleged risk associated with – but not caused by – the Bair Hugger system (the oft-cited 3.8 odds ratio on which Plaintiffs and their experts rely), the reported odds ratio is simply wrong, and there is, in fact, neither a reliable odds ratio nor any statistically significant association. Because the

McGovern study is the only basis that Plaintiffs' medical experts have for quantifying that alleged risk or otherwise opining that the Bair Hugger system causes surgical infections, their opinions are also unreliable and must be excluded. *See*, *e.g.*, *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1322 (9th Cir. 1995) (expert testimony inadmissible where experts "testify to a possibility rather than a probability" and "do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted"); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) ("[W]here [an expert's] ***factual basis***, ***data***, principles, methods, or their application are called sufficiently into question . . . the trial judge must determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline." (emphasis added and internal quotation omitted)); *Adams v. Toyota Mot. Corp.*, 867 F.3d 903, 915 (8th Cir. 2017) (same); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1043-44 (D. Minn. 2007) (Davis, J.) (excluding plaintiffs' general causation medical expert's opinion that was premised upon reanalysis of epidemiological data, because there were "inherent uncertainties in the numerator and denominator used" in the underlying data.).

Plaintiffs' eleventh-hour attempt to downplay the significance of these issues – and, indeed, the McGovern study itself – rings hollow. McGovern lies at the heart of their case and they know it. The myriad of problems with the McGovern study render the testimony of Plaintiffs' medical experts inadmissible, as was the case in the Viagra MDL. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 945, 950 (D. Minn. 2009) (Magnuson, J.) (*Viagra I*). There, the court initially allowed the testimony of Plaintiffs' general causation experts because they relied on a peer-reviewed, published study. *See id.* A closer

examination of the study revealed various data discrepancies, however, which led the court to exclude the experts' testimony upon Defendants' renewed motion. *See id.*; *see also Norris v. Baxter Healthcare Corp.*, 379 F.3d 878, 884 (10th Cir. 2005) (experts' opinions were "not medically or scientifically valid" when experts "completely ignored or discounted without explanation" studies contradicting their conclusions"); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) ("Before any inferences are drawn about causation, the possibility of other reasons for the association must be examined, including chance, biases such as selection or informational bias, and confounding causes."); *Baycol*, 532 F. Supp. 2d at 1043 (D. Minn. 2007) (Davis, J.) ("It is generally accepted that bias in the conduct of a study can materially affect the result and that detection and accounting for bias are standard tools of epidemiology."). The same result should follow here.

In an effort to avoid an adverse ruling, Plaintiffs attempt to bolster their causation theories with company documents and witness testimony lifted out of context – documents and testimony that, in any event, their medical causation experts never considered or relied upon. This is a misguided effort from the start; general causation evidence must come from experts relying on science, not from out-of-context sound-bites taken from a handful of hundreds of thousands of documents produced in this litigation. *See In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 426 (S.D.N.Y. 2016) ("The statements and public positions of Bayer are not scientific literature that an expert would be expected to confront in the exercise of intellectual rigor in the field"); *see also Glastetter*, 252 F.3d at 991 (8th Cir. 2001) (concluding that purported "admissions" excerpted from company memoranda

did not support general causation); *In re Lipitor*, 2016 WL 8739552, at *12, 14 (alleged admission in employee email that Lipitor caused diabetes, "could not replace expert testimony" and was insufficient to preclude summary judgment on issue of general causation). Even if a defendant's employee "admitted" in some stray document that the moon is made of green cheese, that would not make it so.

The examples cited by Plaintiffs further demonstrate why purported "admissions" do not provide a reliable foundation for expert opinions. First, they cite a purported "warning" by Arizant for the Bair Hugger Model 200 series, without noting that the Model 200 was a non-operating-room device that was not used in the surgery of any plaintiff in this litigation, and that does not also involve standard OR measures such as taping and draping, and without noting that the warning concerned patients *who already have infections*. *See* ECF No. 935, Pl. Mem. Opp. at 1; Ex. 1, Decl. of Genevieve M. Zimmerman ("Zimmerman Decl."), ECF No. 950. Second, they claim that Defendants' employee Mr. Van Duren agreed that the Bair Hugger system was associated with increased particle counts, but as the preceding discussion shows, particle counts *decreased* when the Bair Hugger warming unit began warming. ECF No. 935, Pl. Mem. at 38; ECF No. 950, Zimmerman Decl., Ex. 17. Plaintiffs also cite an old draft pre-warming study protocol, Pl. Mem. Opp. at 1-2, Zimmerman Decl., Ex. 2, but they offer no foundation for the document (indeed, they never questioned any witness about it), and it does not even reference the Bair Hugger system in the cited section. Even if these materials said what Plaintiffs claim they say (and they do not), they cannot substitute for reliable expert testimony. *See In re Accutane Prod. Liab. Litig.*, 511 F. Supp. 2d 1288, 1297 (M.D. Fla.

2007) (excluding expert testimony based on "admissions" in company documents; expert "had no idea how they were created, why they were created, or in what context the words were used in the documents"); *In re Lipitor*, 2016 WL 8739552, at *12, 14 (alleged admission by defendant's employee is no substitute for expert testimony and is insufficient to avoid summary judgment).

D. Though the Court Does Not Need to Reach Them, the Opinions of Plaintiffs' Engineering Experts Also Are Inadmissible.

Although the Court may grant summary judgment in Defendants' favor based on the exclusion of Plaintiffs' medical experts alone, it is worth noting some of the reasons why Plaintiffs' engineering experts (to the extent their opinions were otherwise admissible) cannot carry the burden of providing expert testimony that demonstrates general causation.

The opinions of Plaintiffs' engineering experts are derived from the flawed "research" sponsored and conducted by Augustine and his cohorts, the deficiencies of which are addressed in detail in Defendants' motion to exclude the testimony of Plaintiffs' engineering experts. Their opinions are based on nothing more than mere speculation, guesswork, and – in the words of Plaintiffs' expert Elghobashi – "thinking hard," which leads them to opine about theoretical mechanisms through which the Bair Hugger system *may* increase the risk of surgical infections. Expert testimony about theoretical possibilities is neither reliable nor relevant, however, and is therefore inadmissible.

Instead, Plaintiffs' engineering experts must be able to demonstrate – through scientifically convincing evidence – that there *actually is* a mechanism through which the Bair Hugger *actually does* increase the risk of infection. But they never bothered to try.

None of Plaintiffs' engineering experts conducted any independent experiments or other studies to confirm whether use of the Bair Hugger system *actually* increases the presence of infection-causing *bacteria* at the surgical site. And we know from Augustine's secret studies that previous attempts to culture bacteria coming from the Bair Hugger hose failed. Repeatedly.

Plaintiffs' engineering experts were thus left to make educated guesses about whether an increased infection risk *may* exist, based upon (1) unfounded assumptions that an increased particle count necessarily equates to increased bacteria (notwithstanding evidence to the contrary), (2) "thinking hard" about the temperature of air emanating from the Bair Hugger (instead of actually taking a measurement) and assuming it to be nearly thirty degrees warmer than any actual measurement shows, and (3) pontificating about the flight path of "neutrally-buoyant bubbles," as a proxy by which the Bair Hugger system supposedly deposits infection-causing bacteria into a surgical site. But neither guesswork nor "thinking hard" can carry the day. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 361, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort.").

At bottom, and as demonstrated through various submissions to the Court, Plaintiffs are unable to offer any expert opinion that can reliably "rule in" the Bair Hugger system as a cause of their alleged infections. Plaintiffs are thus unable to prove causation under the laws of any state, which is fatal to their claims. Accordingly, summary judgment is appropriate.

II. SUMMARY JUDGMENT IS ALSO APPROPRIATE UNDER MINNESOTA LAW BECAUSE PLAINTIFFS' EXPERTS' THEORIES ARE NOT ACCEPTED BY THE MEDICAL COMMUNITY

As set forth in Defendants' opening brief, summary judgment for Defendants is also appropriate under Minnesota law, because the general causation opinions of Plaintiffs' experts fail to satisfy the *Frye-Mack* standards of admissibility. Plaintiffs' experts' opinions are neither reliable nor generally accepted in the medical or scientific community, and should thus be excluded under *Frye-Mack* and Minn. R. Evid. 702.

In response, Plaintiffs suggest that *Frye-Mack* is somehow inapplicable because their experts' theories are not new or novel (even though they are). Contrary to Plaintiffs' argument, however, the *Frye-Mack* requirements for admissibility are not limited to "new" or "novel" expert opinions; all expert opinions must satisfy basic requirements of reliability. *See Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000) (discussing admissibility of expert testimony under *Frye-Mack* and confirming that "the particular scientific evidence in each case must be shown to have foundational reliability."). As discussed above, the opinions and testimony of Plaintiffs' experts fall far short of satisfying this standard.

Moreover, Plaintiffs' experts' opinions are neither supported by nor "generally accepted" in the medical or scientific community. Collectively, Plaintiffs' experts opine that the Bair Hugger system causes surgical infections. But apart from Augustine and his cohorts, Plaintiffs and their experts are the only parties to reach this conclusion. Indeed, as described in Defendants' opening brief, every independent, scientific authority to consider the issue – including the FDA – has concluded there is no evidence to support

such a claim. *See* ECF No. 762 at 17-20. Under these circumstances, Plaintiffs' experts' general causation opinions cannot credibly be viewed as either reliable or "generally accepted," and are therefore inadmissible under Minnesota law. Defendants are entitled to summary judgment for these reasons as well.

CONCLUSION

For all of the foregoing reasons, and those set forth in Defendants' opening brief, Defendants' motion should be granted. Plaintiffs do not and cannot offer admissible medical expert testimony to prove that the Bair Hugger system causes surgical infections, and are thus unable to prove general causation. Moreover, after the submission of dozens of briefs, all of these facts remain undisputed:

- No peer-reviewed study has ever concluded that the Bair Hugger system causes surgical infections.
- No peer-reviewed study, including McGovern, has ever concluded that there is a causal basis for any positive association between Bair Hugger usage and surgical infections (except Augustine's debunked and fraudulent study).
- No peer-reviewed study has demonstrated that the use of the Bair Hugger system increases surgical infections at a rate above the background risk.
- The FDA has rejected the Plaintiffs' and Augustine's position that the Bair Hugger system causes surgical infections, and recommends the continued use of forced air warming due to proven patient safety benefits, including reduction in surgical infections.

- No treating physician has ever reported to Defendants or the FDA that the Bair Hugger system caused his or her patient to develop a surgical infection.

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Respectfully submitted,

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